FEB - 7 2005

K 043051

510 (k) SUMMARY
AS REQUIRED BY SECTION 807.92(C)

Identification: QuickScreen™ Oxycodone Test (Models 9120, 9120T, 9120X and 9121)

Description: Immunoassay for the qualitative detection of Oxycodone in urine

Name Of Manufacturer:

Phamatech
10151 Barnes Canyon Road
San Diego, California 92121, USA

Intended Use: The QuickScreen™ Oxycodone Test is a rapid, qualitative immunoassay for the detection of the oxycodone in urine. The cutoff concentration for this test is 100 ng/ml. This assay is intended for professional use.

Technology: The QuickScreen™ Oxycodone Test, like many commercially available oxycodone screening test kits, qualitatively measures the presence of oxycodone by visual color sandwich one step immunoassay technology. Examples of such predicate devices include the ABMC RapidOne Oxycodone test (Kinderhook, NY). These devices rely on the basic immunochemical sandwich assay principle of recognition and formation of specific antibody / target analyte / antibody / complexes.

Performance: The product performance characteristics of the QuickScreen™ Oxycodone Test were evaluated in a clinical sample correlation study and a blind labeled spiked study. The results of these studies demonstrate the QuickScreen™ Oxycodone Test to be substantially equivalent to the reported performance characteristics of other commercially available tests for the qualitative detection of the oxycodone in urine. Laboratory studies, using clinical specimens, produced a >99% correlation when compared to the predicate devices.

Conclusion: For the reasons mentioned above, it may be concluded that the Phamatech QuickScreen™ Oxycodone Test is substantially equivalent to a variety of detection tests currently in commercial distribution and is safe in the hands of the professional user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB - 7 2005

Mr. Carl Mongiovi
Vice President
Phamatech Inc.
10151 Barnes Canyon Road
San Diego, CA 92121

Re: k043051
Trade/Device Name: QuickScreen Oxycodone Test Model 9120, 9120T, 9120X, and 9121
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG
Dated: January 5, 2005
Received: January 19, 2005

Dear Mr. Mongiovi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: Phamatech

510 (k) Number K043051:

Device Name: QuickScreen Oxycodone Test Model 9120, 9120T, 9120X and 9121

Indications for Use:

The QuickScreen™ Oxycodone Test is a rapid, qualitative immunoassay for the detection of Oxycodone in urine. The cutoff concentration for this test is 100 ng/mL. This test is intended for professional use.

This test provides only a preliminary test result. A more specific alternate testing method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are observed.

Prescription Use: ___X___ AND/OR Over the Counter: ___
Part 21 CFR 801 Subpart D 21 CFR 807 Subpart C

Concurrence of CDRH Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K043051